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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/594,964  | 09/29/2006  | Tomoki Todo          | 042715-5024         | 1879             |
| 9629 7590 12/04/2008<br>MORGAN LEWIS & BOCKIUS LLP<br>1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| SALIM, ALI REZA   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1648  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/594,964

## Applicant(s)

TODD, TOMOKI

## Examiner

A R. Salimi

## Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s) Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s) Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

This is a response to the amendment filed on 10/03/2008. Claims 1-6, 8 have been canceled. Claims 7, 9, 10-12, 14-16 have been amended. Claims 7, 9-16 are pending before the examiner.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 7, 9, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffin (US 2003/0091537 A1) for reasons of record advanced in the previous Office Action mailed 07/03/08. Applicant argues that Coffin fails to disclose all the limitations of the pending claims. Because Coffin fails to disclose the specific type of cytokine that may be expressed by the recombinant virus. While Applicant admits on the record that Coffin discusses with great detail administration of recombinant virus and suitable doses and carriers. Applicant asserts Coffin fails co-administration of recombinant HSV with IL-18.

Applicant's argument as part of amendment filed 10/03/2008 has been considered fully, but they are not persuasive.

Coffin disclosed a replication defective herpesvirus wherein gamma 34.5 gene, ICP6 gene, and ICP47 are deleted (see claims 1, and 5). Also, he taught the expression of expression

of a cytokine, which reads on IL-18 (see claim 2). Coffin's disclosure is a pioneering invention. At the time Coffin filed IL-18 was well known and Coffin does not have to list each and every cytokine. Still further, he also taught systematic administration of the virus into the tumor (see Paragraph [0053]). The current Applicant has not discovered the IL-18 and certainly has not discovered the recombinant HSV and its application. Coffin's teaching indeed reads on co-administration of a recombinant HSV with IL-18 and anticipates the broad limitations of the now claimed invention. The rejection as it applies to claims 7, 9, 12-14 is respectfully maintained.

***Claim Rejections - 35 USC § 103***

Claims 7, 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (WO 02/076216 A1) and Yamanaka et al (Cancer Immunol. Immunother. 1999, 48(6):297-302) for reasons of record advanced in the previous Office Action mailed 07/03/08. Applicant argues Yamanaka observed that IL-18 alone does not have an anti-tumor effect. Applicant asserts that Yamanaka does not teach HSV. Moreover, Applicant argues the high unpredictability of the art does not render the invention obvious.

Applicant's argument as part of amendment filed 10/03/2008 has been considered fully, but they are not persuasive.

At the onset it appears Applicant has changed the required standard under Section 103. Applicant requires a far higher standard than legally permitted. Applicant tends to dismiss the detail teaching of the above cited art and instead focuses on the unpredictability of the art, which is more appropriate under Section 112. The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any

differences between the claimed subject matter and the prior art, (3) the level of skill in the art. See, Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).

Here, Johnson et al disclosed a herpes virus expression vector wherein ICP47 and gamma 34.5 regions are inactivated (see claims 4, 28). In addition, they taught inactivation of ICP6 region as well (See claim 5). They also taught the method of utilizing the vector in inducing immune response (see claims 6-8). In addition, they taught expression of all types of cytokines (see page 10, lines 30). Hence, they taught the virus in detail and the employment of cytokines to treat tumors. All Applicant has done is administer two different types of cytokines to induce immune response. As it was stated previously Johnson was deficient in teaching combination of IL-18 and IL-12 and for that reason that deficiency was satisfied by teaching of Yamanaka et al. Yamanaka et al taught the efficacy of combination of IL-18 and IL-12. Applicant asserts that because Yamanaka et al did not teach HSV vector then the invention is not obvious. Applicant's understanding of the previously mailed Office Action is rather misplaced. Yamanaka et al augments the deficiencies of the Johnson's teaching and not the other way around. It was clearly stated that Johnson et al disclosed a herpes virus expression vector wherein ICP47 and gamma 34.5 regions are inactivated (see claims 4, 28). And they taught inactivation of ICP6 region as well (See claim 5). Also, they taught expression of all types of cytokines (see page 10, lines 30).

So Applicant has taken a well known virus as taught by Johnson and added another cytokine such as IL-12 to induce better efficacy. But Yamanaka et al had already disclosed that combination of IL-18 and IL-12 would have a synergetic effect.

Thus, the prior art provided the appropriate vector, and the cytokine, i.e. IL-18, that lends to enhanced activity. The art also suggested that combination of IL-12 and IL-18 is beneficial in treating tumors. And one would have been motivated by the above cited art to induce a synergistic effect against cancer cells.

Applicant here has taken a well known vector, and added a well known cytokine, i.e. IL-18, just as Johnson et al had suggested. Then Applicant has added another well known cytokine, i.e. IL-12. But Yamanaka et al had already disclosed the beneficial efficacy of combining IL-12 and IL-18. Therefore, the prior art provided the vector and the cytokine, and the prior art also suggested that combination of IL-18 and IL-12 would be beneficial. The level of skill in this art is rather high. So all Applicant has done is to combine known teachings. Applicants are reminded that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. (2007). The rejection is maintained.

No claims are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/

Primary Examiner, Art Unit 1648

12/02/2008

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